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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,187	06/20/2003	Timothy J. O'Brien	D6064CIP/D2	8237

7590 09/25/2006

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EXAMINER	
HARRIS, ALANA M	

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 09/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/600,187	O'BRIEN ET AL.	
	Examiner	Art Unit	
	Alana M. Harris, Ph.D.	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-52* is/are pending in the application.

4a) Of the above claim(s) *1-11, 18-31 and 36-52* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-17 and 32-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. 20060906
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group III (claims 12-15 and 32-35) in the reply filed on July 17, 2006 is acknowledged. The traversal is on the ground(s) that the kit comprising the elected method should be examined together. This is found persuasive.

The balance of the requirement is still deemed proper and is therefore made FINAL.

2. The Examiner called Dr. Adler and noted claims 16 and 17 were erroneously listed in Group I and should have been listed in Group III. As per the conversation on September 6, 2006 claims 12-17 and 32-35 will be examined in this Action and the correct citing of Groups is listed below.

I. Claims 1-9, 49 and 50, drawn to an polynucleotide and a composition comprising the said polynucleotide, classified in class 536, subclass 23.1.

II. Claims 10, 11 and 46-48, drawn to an isolated and purified TADG-15 protein, classified in class 530, subclass 350.

III. Claims 12-17 and 32-35, drawn to a method for detecting TADG-15 mRNA and a kit for said method, classified in class 435, subclass 6. Claims 32-35 will be examined with Group III to the extent they read on a hybridization assay.

IV. Claims 18-21 and 32-35, drawn to a method of detecting TADG-15 protein and a kit for said method, classified in class 435, subclass 7.1. Claims 32-35 will be examined with Group III to the extent they read on detecting a protein.

V. Claim 22, 23 and 24, drawn to an antibody, classified in class 530, subclass 387.1.

VI. Claim 25, drawn to a method of screening for compounds that inhibit TADG-15, classified in class 435, subclass 7.4.

VII. Claim 26, drawn to a method of inhibiting expression of TADG-15 in a cell, comprising introducing a vector into said cell, classified in class 435, subclass 455.

VIII. Claim 27, drawn to a method of inhibiting a TADG-15 protein in a cell, comprising introducing an antibody into said cell, classified in class 435, subclass 344.1.

IX. Claims 28-31, drawn to a method of targeted therapy to an individual, classified in class 424, subclass 130.1.

X. Claims 36-39, drawn to a method of vaccinating an individual, classified in class 514, subclass 2.

XI. Claims 40-45, drawn to a method of producing immune-activated cells, classified in class 435, subclass 325.

XII. Claims 51 and 52, drawn to a method of treating a neoplastic state, classified in class 514, subclass 44.

3. Claims 1-52 are pending.

Claims 1-11, 18-31 and 36-52, drawn to non-elected inventions are withdrawn from examination.

Claims 12-17 and 32-35 will be examined to the extent they read on detecting a nucleic acid.

Claim Objections

4. Claim 34 is objected to because of the following informality: it recites assays that are not applicable to the elected and examined Group, as well as an incorrect word, "ELIZA" on line 3. Correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 12-17 and 32-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The written description in this case only sets forth SEQ ID NO: 1 as a TADG-15 nucleic acid.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must

convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (*See Vas-Cath* at page 1116). Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115).

Applicants are not required to disclose every species encompassed by a genus. For example as indicated in *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

Applicants broadly claim a kit and an antibody encompassing and specific for a TADG-15, tumor antigen derived gene-15. However, Applicants are not entitled, nor is the specification enabled for the use of all TADG-15 nucleic acid within a kit and probes specific for said an undefined and uncharacterized TADG-15 nucleic acid. Applicant is only in possession of one species of TADG-15 nucleic acid, which is SEQ ID NO: 1. Applicants are not permitted to claim all tumor antigen derived gene-15 nucleic acids and kits that comprise them that are encompassed by the claims, hence not entitled to

the wide breadth of the claims at issue. There is no disclosure, beyond the mention of SEQ ID NO: 1 as a TADG-15 nucleic acid made in the specification, page 14. And as Applicants' claims are written the recitation "tumor antigen derived gene-15 (TADG-15) mRNA" could encompass variants, mutants and proteins from not only humans, but other animals. There is no description of the sites at which variability may be tolerated and there is no information regarding the relation of structure to function. Structural features that could distinguish the compounds in the genus from others excluded are missing from the disclosure.

This is insufficient to support the generic claims as provided by the Interim Written Description Guidelines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645.

Applicants can obviate the instant rejection my amending the claims to reflect that the TADG-15 mRNA of the claims reads specifically on SEQ ID NO: 1.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. "Means for detecting said label" in claim 17 is not commensurate with the endpoint of the method comprised in the kit. It seems that the TADG-15 mRNA is to be detected and not the label. Applicants are requested to clarify.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 12-17 and 32-35 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 11 of U.S. Patent No. 5,972,616 (issued October 26, 1999). Although the conflicting claims are not identical, they are not patentably distinct from each other because the active steps are the same, reading on detecting mRNA bound by a probe with hybridization. And even though the instant

claims contain kit claim the kit is regarded as an intended use and carries no patentable weight.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571) 272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER
09/18/2006

Alana M. Harris, Ph.D.
18 September 2006